benefits and, if so, whether the NCD is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63716, Nov. 7, 2003]

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the SSA or the CMS or unless otherwise prohibited by law.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

§ 405.874 Appeals of carrier decisions that supplier standards are not met.

(a) An entity serving as a National Supplier Clearinghouse must act promptly to determine if any entity submitting a request for a billing number as a Medicare supplier of part B items meets the standards set forth in part 424. Effective July 1, 1993, the National Supplier Clearinghouse must accept, reject or request additional information within 15 days of the receipt of an enrollment application.

(b) If the National Supplier Clearinghouse disallows an entity's request for a billing number or revokes, with the concurrence of CMS, an entity's billing number, the National Supplier Clearinghouse notifies the entity by certified mail. Revocation is effective 15 days after the National Supplier Clearinghouse mails notice of its determination. The carrier disallows payment for items furnished by the supplier beginning with that effective date. The notice must inform the entity of the reason for the rejection or revocation, its right to appeal, the date by which it must file that appeal (90 days after the postmark of the notice) and the address to which the appeal must be sent in writing.

(c) A fair hearing officer not involved in the original determination to disallow an entity's request for a billing number, or to revoke an entity's billing number, must schedule a hearing to be held within one week of receipt of an appeal, or later at the request of the entity. Both the entity and carrier may offer evidence. The hearing officer issues notice of his/her decision within 2 weeks of the hearing. The notice is sent by certified letter to CMS, the carrier, and the appealing entity. This notice must include information about the supplier's further right to appeal, the carrier's right to appeal, the date by which the appeal must be filed (90 days after the postmark of the notice) and the address to which the appeals

must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to CMS.

(d) A CMS official, designated by the Administrator of CMS, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The CMS official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the CMS of the appeal. Notice of the CMS official's decision—

(1) Is issued within two weeks of when the last information is received is received by the CMS official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the CMS official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a CMS official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which CMS has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under